PURITAN BENNETT tyco Healthcare

GoodKnight® 420 Evolution

Patient Manual

Ref. : M-139DFU05-70 Revision C

List of patient manual revisions
GoodKnight® 420 Evolution

The pages below are included in the American version of the patient manual Ref. M-139DFU05-70 revision C.

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Reference or revision	Description	Date
M-139DFU05-70 revision A.	Creation of the manual	December 2002
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PURITAN BENNETT tyco Healthcare

The Puritan Bennett ***GoodKnight* 420 Evolution** device (*GK*420 Evolution) is intended for the treatment of patients suffering from Obstructive Sleep Apnea Syndrome (OSAS). The main characteristic of this pathology is the occurrence of multiple respiratory events caused by contraction of the upper airways, that disturb sleep. The *GoodKnight* 420 Evolution delivers a Continuous Positive Airway Pressure (CPAP) that prevents the upper airways from becoming obstructed thus eliminating apneas.

It is essential for you to understand the use of this device. Therefore, please read this manual carefully before using the *GoodKnight* 420 Evolution.

The information contained here is intended to help you use this device under optimum conditions of safety and operation. For any questions relating to the equipment and its use, contact your medical team or your home care provider.

Your doctor has decided on the treatment of your illness. He/she has prescribed the different parameters that the hospital or your home care provider will set. The home care provider will adjust these parameters, as needed.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

***GoodKnight*® is** a registered trademark of Nellcor Puritan Bennett Inc.

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BEFORE STARTING

Safety instructions

In order to ensure the appropriate use of your ***GoodKnight* 420 Evolution**, please read all the information contained in this operator manual. Pay special attention to the passages preceded by the following terms:

WARNING	Indicates a potential risk of death or accident to you or caregiver.
CAUTION	Information to avoid damaging equipment or losing data.
NOTE	Tips for ease of use of the *GoodKnight* 420 Evolution device.

WARNINGS

1. Before you use the ***GoodKnight* 420 Evolution** device, examine it as specified in the chapter "Checking the components" (See page 3).
2. If you need an additional supply of oxygen, carefully observe the safety instructions for using oxygen given in the chapter "Starting treatment". (See page 11).
3. Only use the accessories that have been given to you by your home care provider. Check that you have the instructions for using each of these accessories and read through them.
4. Use only the specific power supply module provided with the device.
5. Do not use the device in the presence of inflammable fumes.
6. Follow the device's installation instructions as specified in this manual in the chapter "Installation". (See page 7). In particular, keep the machine away from any sources of water.
7. Do not accidentally or intentionally obstruct the air outlet or any other opening in the device or the respiratory circuit.
8. Do not introduce liquids or objects into the air outlet.
9. If you experience any of the following symptoms when you use the *GoodKnight* 420 Evolution, discontinue use and contact your home care provider: dryness in your nose and airways; skin sensitivity; runny nose; earache; sinus trouble; daytime drowsiness; mood changes; disorientation; irritability; or, memory loss.
10. Contact your home care provider in the event of any malfunction of the *GoodKnight* 420 Evolution, whatever it may be. Maintenance of this equipment should only be performed by trained and authorised personnel. Do not attempt to open the device.
11. The air flow produced by the *GoodKnight* 420 Evolution can be as much as 7°F higher than the room temperature. Exercise caution if the room temperature is warmer than 90°F.

Indications for use

The ***GoodKnight* 420 Evolution** device is indicated for use in the treatment of obstructive respiratory sleep disorders, particularly Obstructive Sleep Apnea (OSA). Patients who have been diagnosed with this condition may use the *GoodKnight* 420 Evolution if they weigh over 66 lbs (30 kg) and are able to breathe spontaneously. Their treatment may be administered either in a homecare or hospital environment.

Precautions for use

Clinical research indicates that CPAP therapy may be contraindicated for patients with any of the following pre-existing conditions:

- Extremely low blood pressure
- Pneumothorax or pneumomediastinum (collapsed lung/air trapped in the lung tissue or in the tissue between the lungs)
- Severe bullous emphysema or previously complicated by pneumothorax
- Massive epistaxis or previous massive epistaxis (nose bleed)
- Decompensated cardiac insufficiency or hypotension, especially in case of depletion in blood volume or cardiac rhythm disorder (inadequate blood pressure)
- Pneumoencephalus (air trapped around the spinal cord), traumatism, or recent surgery with the after-effect of a cranio-nasopharyngeal fistula (abnormal opening between head, nose, and throat)
- Acute sinusitis (inflammation of the sinus cavity), otitis media (earache), or perforation of the tympanic membrane (eardrum)
- Severe claustrophobia (fear of being shut up in a confined space).

Modem transmissions

When it is time to review the information stored on your *GoodKnight* 420 Evolution, your home care provider may set up a modem connection, which is a telephone communication device. The modem translates computer signals into telephone signals that are sent and converted to computer data that will be reviewed with SilverLining 3 special software.

NOTE

Your home care provider will set up the modem connection, and instruct you on how to use it.

Checking the components

To use the ***GoodKnight* 420 Evolution** with its specific electrical power supply, you must be provided with the following items at least:

- A spiral tubing enclosing a second small transparent tubing
- A nasal-mask (often called an "interface") and all related accessories as specified in the instructions for using this interface.

In addition to these accessories, your doctor may have prescribed the use of a humidifier. In this case, ensure that you have all the accessories required for this humidifier, as specified in its operating instructions.

In the event that an additional oxygen supply is needed, you must also have an adaptor (but only in cases where the oxygen supply is not fitted directly onto the interface). Refer to the chapter "Fitting an oxygen adaptor". (See page 8)

Carefully examine the *GoodKnight* 420 Evolution and each accessory. Check the tubings for damage. The interface should not have any cracks or distortion in the cup and bellows (part of the mask coming in contact with the face).

Verify that the *GoodKnight* 420 Evolution and the specific power supply module have no external damage, verify that there is no obvious fault. Connect the device to the mains using the power supply module, referring to steps 4 and 5 of the chapter "Standard installation". (See page 7).

The type of the device is displayed for a few seconds then the following standby screen showing the hour (the value displayed is given as a guide only) ; the device's display should show the time in the 24 hour format:

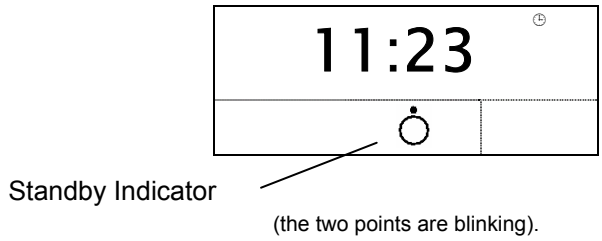

Figure 1 – View of the display when the device is in standby mode

If the device was disconnected while it was running, the screen displays the pressure. The device shows the same mode as at the time of the power supply cord disconnection and is set on the pressure used at the disconnection time.

Start the device by pressing the **ON/OFF** button (see Figure 2, page 5). The turbine should start up and the noise should be regular.

To stop the device, press the **ON/OFF** button and unplug the power supply lead from the mains.

WARNING

In the event of problems or if you discover any anomaly, do not start the treatment and contact your home care provider.

DESCRIPTION OF THE DEVICE

The ***GoodKnight* 420 Evolution** device is powered from an external power supply and equipped with specific accessories. The device is described below. See figures 2, 3 and 4 on page 5.

1. Display

Shows various kinds of information such as the pressure delivered, the settings of the device or the time. For additional information, refer to the chapter "Using the GoodKnight 420 Evolution to access information". (See page 14).

2. Information access button

Allows you to access various kinds of information regarding the device. For further details, refer to the chapter "Using the GoodKnight 420 Evolution to access information". (See page 14).

3. Ramp button

Used for starting or stopping the pressure increase ramp (for additional information, refer to the chapter "Using the ramp" on page 12). It is also used to decrease the value of the parameters during the device settings.

4. ON/OFF button

Used for switching the device on or off. It is also used to increase the value of the parameters during the device settings.

5. Pressure port

This is the connector onto which the small tubing is connected. For additional information, refer to the chapter "Installation". (See page 7).

6. Outlet connector

This is the air outlet onto which the large tubing is connected. For further information, refer to the chapter "Installation". (See page 7).

7. Serial communication port

This connector is intended to be used solely by your physician or your home care provider. Do not connect it to anything.

8. Supply connector

Used for powering the device from the specific power supply module or from an external battery. For additional information, refer to the chapter "Installing an external battery". (See page 10).

9. Air inlet filters

These filters prevent dust from entering the device and the air flow. Please refer to the chapter on "Maintenance and cleaning instructions" for additional information on the maintenance instructions for these filters. (See page 17).

The items in the Figures below are described on page 4.

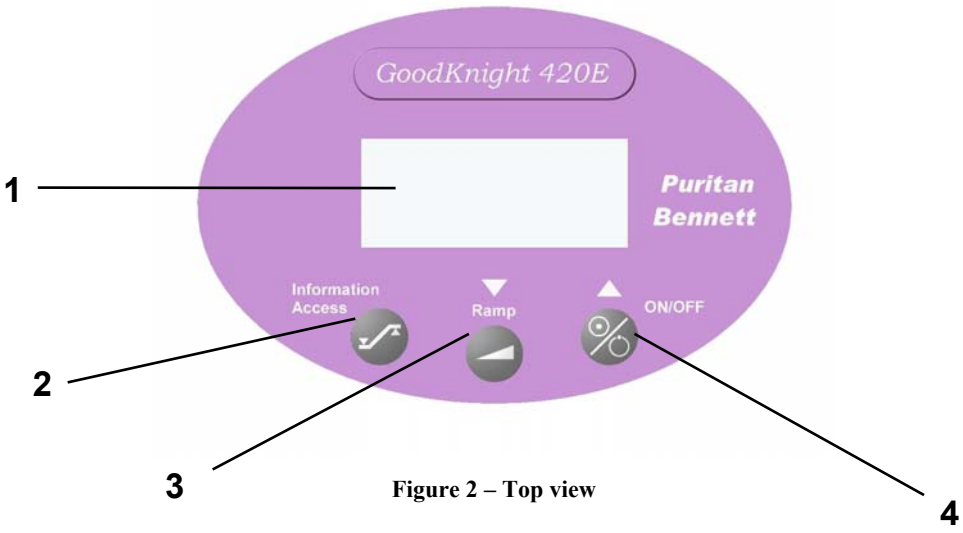

Figure 2 – Top view

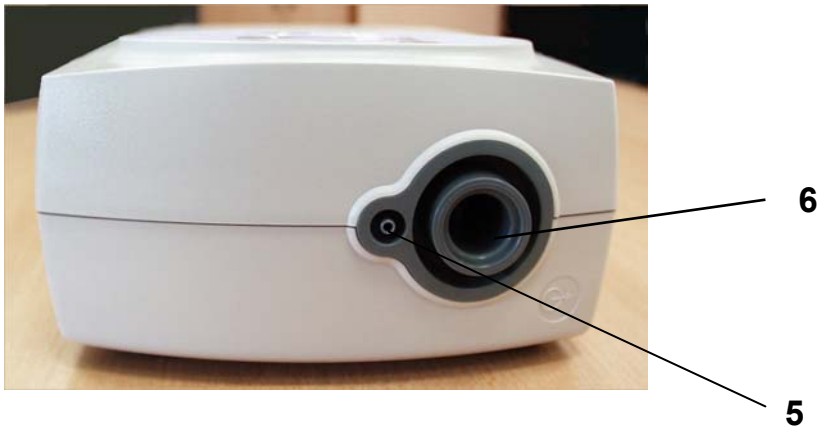

Figure 3 – General view

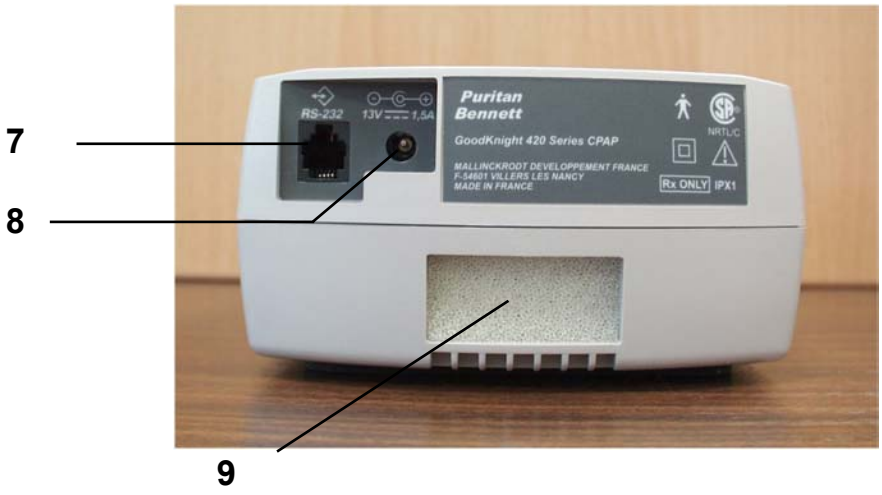

Figure 4 – Rear view

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INSTALLATION

This chapter shows you how to connect the various accessories and cables to your *GoodKnight* 420 Evolution. Before starting the installation, examine your device and its accessories. Refer to the chapter "Checking the components" (See page 3).

CAUTION

When you are ready to use the *GoodKnight* 420 Evolution, place it on a stable surface. Avoid placing it too near a wall or any other obstacle that could hamper the intake of air into the device.

Standard installation

1. Connect the spiral tubing to the device. To do this, connect the small tubing that emerges through one of the large ends of the spiral tubing, to the pressure port (See Figure 3, page 5). Connect the large end of the spiral tubing onto the outlet connector of the machine (See Figure 3 page 5 and Figure 5 page 7).

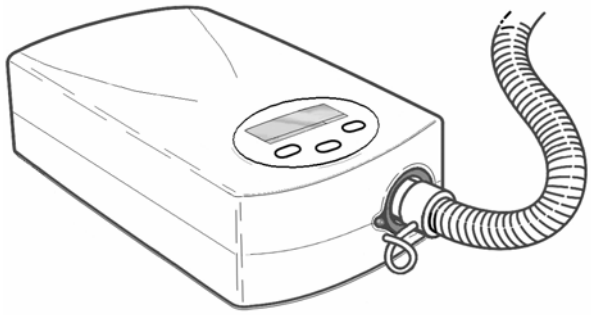


Figure 5 – Connection of the spiral tubing to the device

WARNING

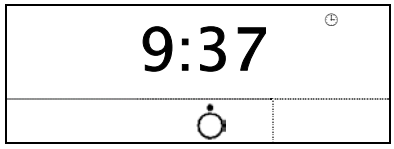
Take care that the small tubing is not twisted or bent.

2. Prepare the interface as described in its instructions for use.
3. Connect the interface to the spiral tubing's free end.
4. Connect the cable of the power supply module to the supply connector located on the back of the device (see Figure 4, page 5).

CAUTION

Use only the specific power supply module provided with the device.

5. Connect the plug of the power supply module to the electrical outlet. The type of the device is displayed for a few seconds then the following standby screen showing the hours and the minutes in 24 hour format:



The two points are blinking.

6. The device is ready to operate. Please refer now to the chapter "Use" (see page 11).

Fitting an oxygen adaptor

Substitute the following step for step 1 of the standard installation procedure:

- Connect the oxygen adaptor onto the device's outlet connector and connect the other end of the adaptor onto the large end of the patient tubing. (see Figure 6). Connect the small tube that emerges through one of the patient tubing large ends to the pressure port (see Figure 3, page 5).

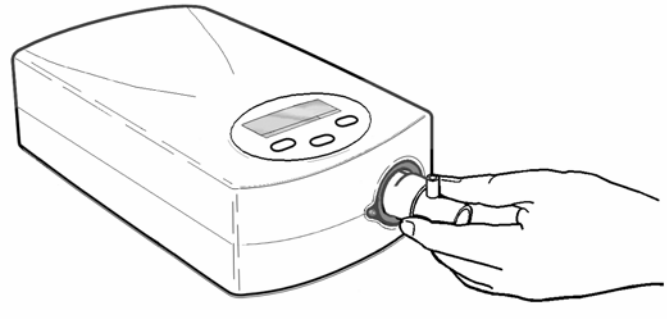


Figure 6 – Connecting the oxygen adaptor to the device

To continue installing the equipment, proceed to steps 2 to 6 of the standard installation.

WARNINGS

- **Always follow the instructions of your physician and home care provider in the event of using oxygen.**
- **Do not smoke in the presence of oxygen.**
- **Do not inject oxygen through the air inlet of the GoodKnight 420 Evolution.**
- **Carefully follow the start-of-treatment and end-of-treatment steps as described in the chapter on "Use" (see page 11).**
- **If supplemental oxygen is used, the oxygen flow must be turned off when the *GoodKnight* 420 Evolution is not operating. If the oxygen flow is left on when the device is not operating, oxygen delivered to the interface circuit may accumulate within the *GoodKnight* 420 Evolution. Oxygen accumulated in the device could create a fire hazard.**

CAUTION

If the supplemental oxygen flow rate is fixed, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, interface selection, and the leak rate.

Installing a humidifier

Refer to the humidifier instructions for additional information on assembly and safety precautions.

WARNING

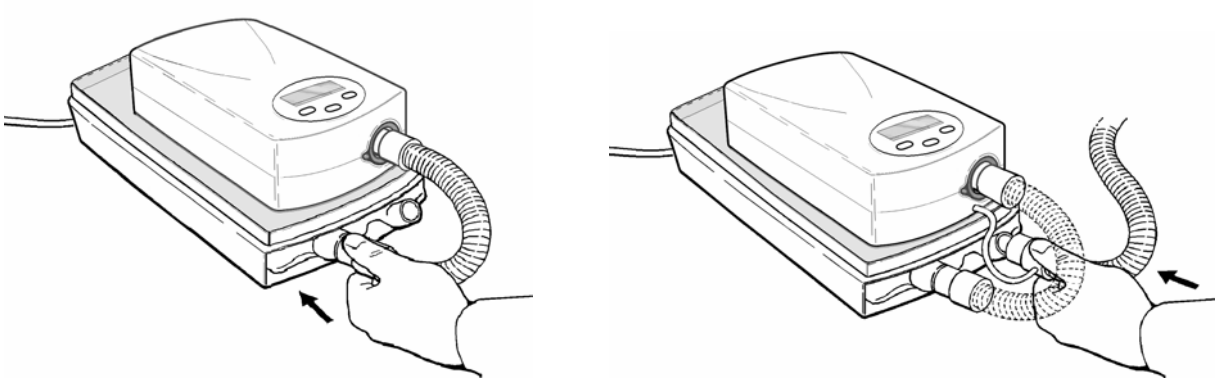
The humidifier must be filled with distilled water before being connected to the GoodKnight 420 Evolution.

CAUTION

In order to avoid water damage, make sure that the humidifier is always placed lower than the GoodKnight 420 Evolution unit.

Substitute the steps below for step 1 of the standard installation procedure:

1. Connect one of the ends of the short humidifier hose onto the outlet connector of the device. (see Figure 3 page 5 and Figure 7).
2. Connect the other end of the short humidifier hose onto one of the humidifier's connectors.



Steps 1 and 2 Steps 3 and 4

Figure 7 – Connecting the humidifier to the GoodKnight 420 Evolution

3. Connect the small tube that emerges through one of large patient tubing's ends to the pressure port (see Figure 3 page 5 and Figure 7).
4. Connect this same end of the long patient tubing onto the humidifier's second connector.

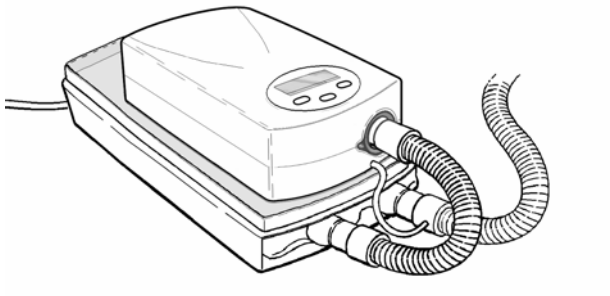


Figure 8 – View of the humidifier connected to the GoodKnight 420 Evolution

You can then resume with steps 2 to 6 of the standard installation for installing the equipment.

Installing an external battery

The ***GoodKnight* 420 Evolution** can be powered by an external 12-Volt car battery by using a optional cable provided for this purpose.

CAUTION

- **Do not use any battery power cable other than the optional cable supplied with the *GoodKnight* 420 Evolution. There would be a risk of damaging the device and your battery if you use unapproved accessories.**
- **Use only 12-Volt DC sources and ensure that the polarity connections (+ and -) are correct.**

The device can be used for 8 hours at least with a fully charged car battery in normal operation conditions.

To install the battery power cable, substitute the following steps for steps 4 and 5 of the standard installation procedure:

1. Connect the battery power cable onto the battery supply connector located on the back of the *GoodKnight* 420 Evolution (see Figure 4, page 5).
2. Connect the other end of the cable directly onto the battery.

NOTE

Before using the battery, always be sure it is fully charged.

The *GoodKnight* 420 Evolution can be powered through a vehicle cigarette lighter by using the cable provided for this purpose.

To do so, replace steps 4 and 5 of the standard installation by the following steps:

1. Connect the battery power cable onto the supply connector at the back of the device (see Figure 4, page 5).
2. Connect the other end of the cable directly onto the cigarette lighter-plug.

USE

This chapter shows you how to use the device after installing it as described in the previous chapter. It also shows you how to use the pressure increase (ramp) function and how to access information on settings (you will not be able to alter these settings, only view them).

WARNING

In the sections, "Starting treatment" (page 11) and "Stopping treatment" (page 12), follow the instructions carefully. The instructions must be followed in order, or an accident could occur, especially when oxygen is involved.

Starting treatment

Once the *GoodKnight* 420Evolution has been properly installed, follow these instructions:

1. Start the device by pressing the **ON/OFF** button .
   The display shows the pressure available as well as the operation and compliance indicators. (See Figure 9).

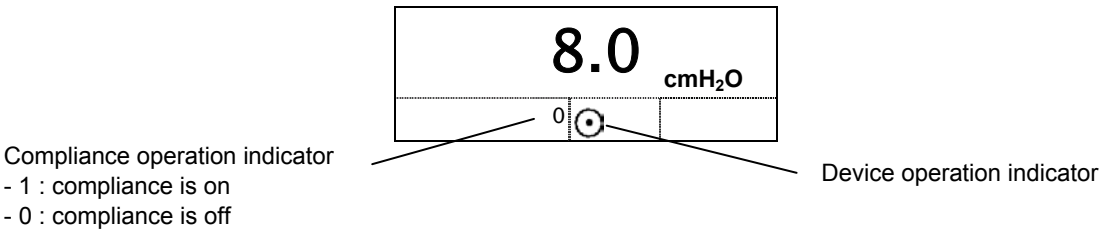


Figure 9 – View of the display when the device is running

NOTES

- The pressure unit displayed (hPa or cmH_2O) can be modified by the Practitioner.
- The compliance operation indicator is only displayed after the *GoodKnight* 420 Evolution has been operating for 15 minutes.

2. Put the patient interface (nasal mask) in place according to the instructions for use. If an interface with exhalation vent is used, it includes a hole by which the exhaled gases will be flushed and could not be rebreathed. If an interface without exhalation vent is used, your Homecare Provider must provide you with an adaptor allowing gases flushing as close as possible to the nose. **Breathe normally** with your mouth closed.

   WARNING

   A patient interface with hose should not be worn, unless the CPAP device is turned on and operating properly. The vent hole(s) associated with the interface should never be blocked. This CPAP device is intended to be used with interfaces (or connectors) that have vent holes to allow a continuous flow of air out of the interface. When the CPAP device is turned on and is functioning properly, fresh air from the CPAP device flushes the exhaled air out through the interface vent hole. However, when the CPAP device is not operating, adequate fresh air will not be provided through the interface, and exhaled air may be rebreathed. Rebreathing exhaled air for longer than several minutes could, in some circumstances, lead to suffocation.

3. If you are using a heated humidifier, turn it on according to the instructions for use.
4. If you are using oxygen, open the flow now.

WARNINGS

- **When the device is in operation mode, check that it delivers an air flow. If the device is not properly operating, stop it immediately and contact the home care provider.**
- **At lower CPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.**

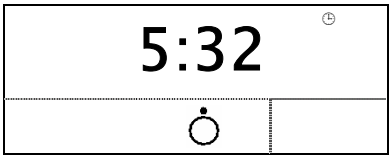
Stopping treatment

When the device is operating, follow the instructions below to discontinue the treatment:

1. If you are using oxygen, stop the flow now.
2. Remove the interface (nasal mask).
3. If you are using a heated humidifier, turn it off according to the instructions for use. Disconnect the humidifier from the unit.

   CAUTION

   Do not leave the humidifier connected to the unit or to the tubing when the humidifier is not in use, as humidity could enter the device or the sensing line and degrade device performance.
4. Turn the device off by pressing the **ON/OFF** button. The device will return to standby mode and display the following standby screen showing the time:



CAUTION

Check that no humidity appears in the tubing, particularly in the sensing line. If so, let the tubing dry before you use it again.

Using the ramp

First of all adjust the starting ramp pressure of your ***GoodKnight* 420 Evolution** device by observing the following instructions:

NOTE

If the ramp time is set to zero, this adjustment is not possible, since the pressure settings are not accessible.

The initial ramp pressure can be set to a value between 4 cmH_2O and the pressure level prescribed by your physician. This function allows you to set the appropriate pressure level to enable you to fall asleep. . To access the parameter setting menu, just press for a second the **Information Access** button, whether the device is on standby or in operation (see Figure 10).

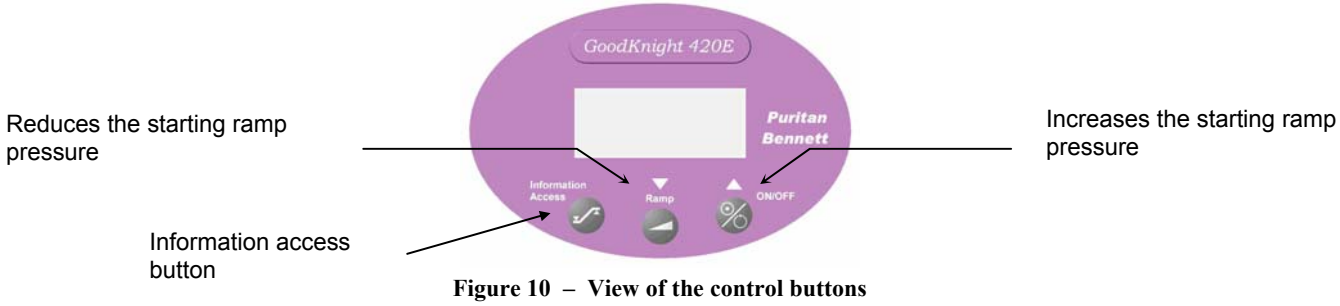
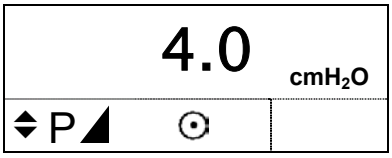


Figure 10 – View of the control buttons

Then, in order to scroll through the settings, continue to press the **Information Access** button, the number of times required for displaying the screen below:



The starting ramp pressure value can then be changed by using the **ON/OFF** key (up) and **Ramp** key (down).

The ramp function enables gradual increases in the delivered pressure. The pressure level may be decreased at nightfall to help you to fall asleep. You can also use this function if you have to get up during the night and have difficulty going back to sleep. The pressure rise time up to the final pressure is prescribed by your physician and the setting carried out by your home care provider is between 0 (no progressive rise) and 30 minutes, in 5-minute increments. The ramp may have been preset to 0, according to your physician's prescription. In this case, the ramp function is disabled, and pressing the Ramp button on the front panel of the *GoodKnight* 420S has no effect. (see Reference 3 in Figure 2, page 5).

1. To start the ramp, just press the Ramp button when the device is on. The pressure will decrease to a low set value, then increase progressively up to the prescribed pressure level, so you won't be awakened. The device will run normally, delivering a treatment pressure throughout the night, unless you press the Ramp button again, in which case the pressure will drop down again to the ramp level that you have selected.
2. To end the ramp, press the Ramp button again and the function will be disabled. It is possible to reset the ramp time by reactivating the ramp function (the ramp indicator lights up when this is activated).

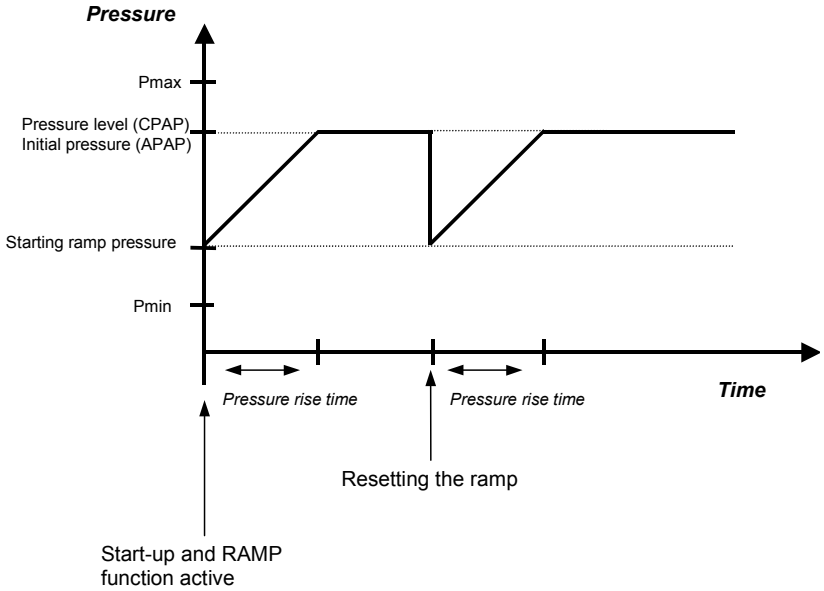


Figure 11 – Changes in pressure over time when activating the ramp function

Using the GoodKnight 420 Evolution to access information

The display enables you to view the information on the settings of the ***GoodKnight* 420 Evolution**. (See reference 1 in Figure 2 on page 5).

The setting information is accessible whether the device is on standby or in operation. To access this information, just press the **Information Access** button for one second. (See reference 2 in Figure 2 on page 5).

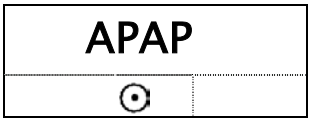
You will access additional data each time you press the key. Only those settings that display the ▲▼ symbol are changeable in this mode of access.

NOTE

In the following screens, the device is shown in operation mode and all the values are given as a guide only.

Press for one second on Information Access button

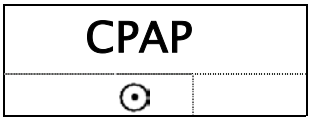
The screen displays:



- **The *GoodKnight* 420 Evolution operating mode:**

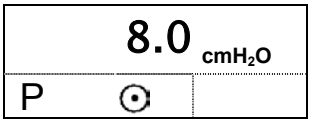
If APAP is displayed: the device runs in automatic mode, the device's pressure is best suited to your pathology.

or



If CPAP is displayed: the machine delivers a constant pressure.

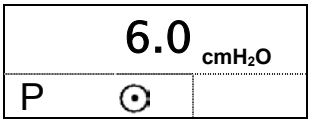
Press Information Access button



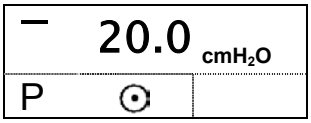
- **The pressure level set** by your physician (corresponding to the pressure prescribed when the device is operating).

When the device is in CPAP mode, a single value is displayed.

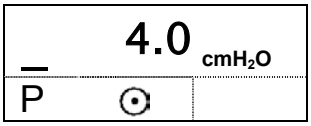
When the device is in APAP mode, three setting values may be viewed successively by pressing the information access key each time.



Initial pressure

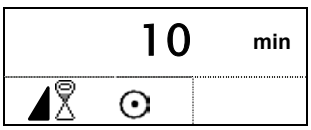


Maximum pressure



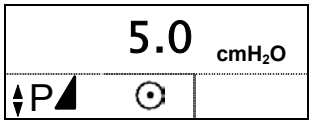
Minimum pressure

Press Information Access button



- **The ramp time prescribed** by your physician (period of time over which the pressure gradually increases from the starting ramp pressure to the pressure level).

Press Information Access button



- **The starting ramp pressure** (pressure level at the beginning of ramp); this parameter is adjustable and visible only if the ramp time is other than 0.

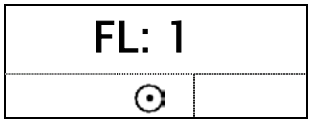
  The symbol ▲▼ shows that the parameter is adjustable. You can increase or lower the value set by using the ON/OFF (up) key or Ramp key (down). For further details, refer to the chapter "Using the ramp" (see page 12).

Press Information Access button

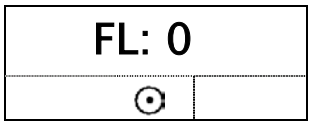
- **The validation of pressure increase commands on flow limitation run,** set by your doctor.

  NOTE

  This function is accessible only if the machine is running in APAP mode.

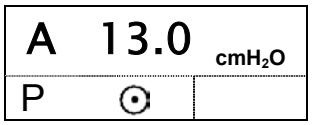


The command is enabled.



The command is disabled.

Press Information Access button

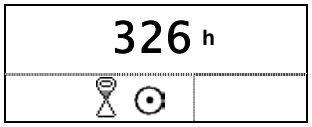


- **The maximum pressure for the commands on apnoea**

  NOTE

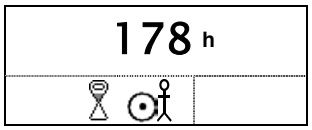
  This function is accessible only if the device is running in APAP mode.

Press Information Access button



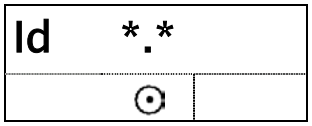
- **The hour meter value** (device operating time). The hourglass symbol stands for "time".

Press Information Access button



- **The compliance meter value** (time during which the patient has breathed with the device). Hourglass and human symbols stand for "patient time".

Press Information Access button

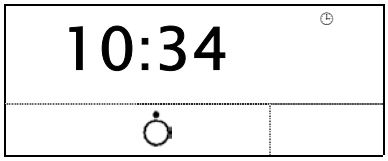


- **The *GoodKnight* 420 Evolution** on-board **software version.**

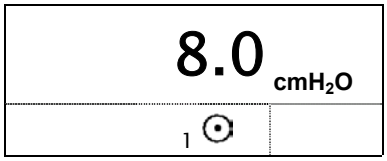
  The version number is shown in two digits (*), for example the screen may display : Id 1.0.

Press the information access button again to exit the parameter setting menu.

The display will again show one of the following two screens indicating the status of your device (the values are given as a guide only).



The device is on standby.



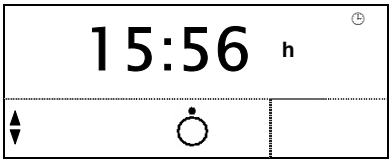
The device is running.

NOTE

Exit from the parameter setting menu takes place automatically when you do not press any key for 30 seconds.

Setting the time

You can set the time only when the device is on standby. To do so, just press and hold the **Ramp** button for one second (see Reference 3 in Figure 2, page 5). Then while continuing to hold the **Ramp** button down, press the **ON/OFF** button (see Reference 4 in Figure 2, page 5). If you release the pressure on the buttons, the symbol of adjustment ▲▼ appears under the time, as shown on the next screen:



NOTE

The time will only be displayed in a 24-hour format. Thus, 15:56 represents 3:56 P.M.

The letter h indicating the hour blinks, you can then set it using the **Ramp** and **ON/OFF** keys.

To set the minutes, just press the **Information Access** button, the symbol of minutes blinks in its turn and you can set the time by following the same procedure as you did for hours.

Press the **Information Access** button again to exit the menu.

NOTE

Exit from the parameter setting menu takes place automatically when you do not press any key for 30 seconds.

LIST OF AUTHORIZED ACCESSORIES

Below you will find the accessories that can be used with the ***GoodKnight* 420 Evolution** equipment.

Interfaces

Adam Pillows (7 sizes):

P/N's S-616323-00A, S-616324-00C, S-616325-00A, S-616355-00C, S-616356-00C, S-616357-00C, Y-101969-00.

Adam CPAP systems:

P/N's Y-100871-00, Y-100872-00, Y-100873-00, Y-100874-00.

SoftFit Interface System:

P/N's S-133335-00, S-133336-00, S-133337-00, S-133338-00, S-133339-00, S-133340-00.

SoftFit Ultra Interface System:

P/N's Y-233335-00, Y-233336-00, Y-233337-00, Y-233338-00, Y-233339-00, Y-233340-00.

Nasal interface Breeze:

P/N Y-101400-00.

DreamSeal™ mask:

P/N Y-102616-00, Y-103059-00, Y-103074-00A.

Tubing

6 ft long patient tubing (with internal pressure line):

P/N Y-261000-27.

8 ft long patient tubing (with internal pressure line):

P/N Y-261000-30.

Other Accessories

Oxygen adaptor:

P/N Y-616155-03B.

Heated humidifier:

Fisher & Paykel HC100.

Air inlet filter:

P/N M-413950-02.

Thin optional filter:

P/N M-413950-04.

Serial connection cable:

P/N M-213930-04.

Battery cable:

P/N M-213930-02.

Battery cable/cigarette lighter plug:

P/N M-213930-03.

Carrying case:

P/N M-213930-01.

Modem kit P/N M-213930-12 includes modem cable and adaptor:

– modem cable P/N M-213530-11

– modem adaptor P/N M-213930-05.

MAINTENANCE AND CLEANING INSTRUCTIONS

In order to ensure that you use your ***GoodKnight* 420 Evolution** safely and efficiently, please observe the maintenance instructions specified below.

GoodKnight 420 Evolution

The hard plastic case protecting the internal components of the ***GoodKnight* 420 Evolution** does not require any special maintenance. When necessary, clean the device by using a soft cloth dampened with warm soapy water. Dry the device thoroughly.

WARNINGS

- **Always unplug the *GoodKnight* 420 Evolution before cleaning it.**
- **Do not use a spray cleaner. This is because residues may lodge in the air outlet, the foam filter, or inside the device. This can cause irritation of the airways.**
- **Do not submerge the device in water.**
- **Do not allow water to run onto the *GoodKnight* 420 Evolution, or drip into any of its openings.**
- **Never use the *GoodKnight* 420 Evolution without verifying that the filter has been installed.**

Air inlet filters

Change the filters as soon as they are torn or dirty (refer to Reference 9 in Figure 4, page 5).

Clean the outer foam filter at least once a week; or, more often if necessary, in the following way:

1. Remove the filter and wash it with warm mild soapy water.
2. Rinse thoroughly to remove all soap.
3. Pat the filter dry with a towel.
4. Allow the filter to dry completely before re-installing it.
5. Replace the filter at the back of the device.

The high-efficiency white fabric filter (this optional filter is available separately) cannot be washed, it must be changed at least once a month, or more often if it is visibly dirty.

WARNING

Never use the *GoodKnight* 420 Evolution without an air inlet filter.

Tubing

Please refer to the cleaning instructions that were sent to you with the tubing.

Nasal interface

Please refer to the instructions for use that were given to you with your nasal interface.

Humidifier

Please refer to the instructions for use that were given to you with your humidifier.

Oxygen adaptor

Please refer to the instructions for use that were given to you with the oxygen adaptor.

TROUBLE-SHOOTING

PROBLEM	PROBABLE CAUSE	SUGGESTION
Discomfort due to a feeling of the pressure being too high.	Pressure of the *GoodKnight* 420 Evolution.	Adapting to the nasal pressure takes a while. Try to use the pressure increase ramp when you go to sleep (see the chapter "Using the ramp" page 12). Relax and breathe slowly through your nose.
	The *GK*420 Evolution is not set in APAP mode.	The pressure may vary during use. If you feel that the device is not set to the correct pressure, contact your service provider to have the equipment checked.
The device is not delivering the correct pressure (display).	The pressure port tube is not connected.	Check that the small pressure port tube is properly connected to the device.
	Moisture is getting into the pressure port tube.	Dry the small tube. To do this, connect the patient tubing onto the device, leaving the small tube disconnected, block up the large tubing with your hand, turn the device on. Repeat if necessary.
	The ramp is enabled.	Check whether the ramp indicator is displayed. Press the Ramp button to cancel the function (see Reference 3 in Figure 2, page 5).
Dry or irritated nose or throat.	The air is too dry.	Humidify the air in the room using a humidifier. Ask the medical-technical team to obtain a humidifier for your CPAP.
Cold nose.	The room temperature is too low.	Increase the temperature of the room or place the tubing under the blankets to reduce heat loss.
Runny nose.	Reaction to the air flow and pressure.	Try high efficiency filter if problem persists. Contact your physician.
The *GoodKnight* 420 Evolution is delivering air that is too hot.	The air inlet filters may be dirty. The air inlet is clogged.	Clean or replace the filters as the case may be (refer to the chapter on "Maintenance and cleaning instructions", page 17). Move any linen, bedding or clothing away from the *GoodKnight* 420 Evolution.
	The room temperature is too high.	Lower the thermostat for the room. Make sure that the device is away from any heat source.
		Remove the hose from under the blankets.
Pain in the nose, sinuses or ears.	Sinus infection or nasal congestion.	Contact your physician or home care provider immediately.
Dryness or irritation of the eyes.	Air leak around the interface.	Reposition the interface. Ask your physician or the home care provider to try different sizes of interfaces.

PROBLEM	PROBABLE CAUSE	SUGGESTION
Redness of the skin in contact with the interface.	The headgear is too tight or too small. Allergic reaction to the components of the interface.	Adjust the headgear. Contact your physician or the home care provider to try on interfaces of different sizes. Stop using the interface. Contact your physician or home care provider.
Recurrence of the first symptoms of sleep apnea syndrome.	The *GoodKnight* 420 Evolution is not set to the correct pressure or is not operating correctly. Your physical condition or your pressure needs have changed.	Ask the home care provider to check the operation of the *GoodKnight* 420 Evolution. Contact the ordering physician or home care provider.
The *GoodKnight* 420 Evolution does not come on (no display).	Verify that the power supply module is properly connected. No AC power. The fuse of the device has blown.	Check the connections between the power supply module, the device and the electric outlet. Use another appliance, such as a lamp or radio to check that the AC power supply is present at the outlet. Contact your physician or home care provider.
The *GoodKnight* 420 Evolution is not running properly and seems to be subject to interference.	Excessive electro-magnetic interference.	Move the device away from sources of interference, such as halogen lamps and cell phones.
In 01 is displayed.	A major leak (disconnection) has been detected in the patient circuit.	This message disappears as soon as the interface is connected and you have breathed 3 or 4 times, or if you press the ON/OFF button twice. Otherwise, check the patient circuit connection.
In 02 is displayed.	Over pressure has been detected by the device for more than 10 seconds.	Examine the connection of the small pressure port tube. Verify that it is not obstructed and that it is properly clean and dry (see the instructions for using the patient circuit).
In 03 appears on the display.	Reduction of the power supply voltage.	Check the connections between the power supply module, the device and the mains socket. Unplug the supply module, then connect it again to the mains. If the problem remains, contact the home care provider. Check the 12 volt DC battery and replace it, if necessary. If the problem remains, contact the home care provider.
Er XX appears on the display. (XX = 2 digits).	The device has detected an operating fault.	Call your home care provider.

TECHNICAL CHARACTERISTICS

GoodKnight 420 Evolution performance

Pressure range of the *GoodKnight* 420 Evolution :	4 cmH_2O to 20 cmH_2O ± 1 cmH_2O adjustable by increments of 0.5 cmH_2O
Maximum achievable pressure at the patient connection port under single fault condition:	24 cmH_2O
Ramp time:	0 to 30 minutes ± 1 minute device adjustable by increments of 5 minutes
Sound level measured in accordance with: PrEN ISO 17510-1 :2001	27.4 dBA
Maximum sound level:	31 dBA à 10 cmH_2O
Lifetime of the battery soldered onto the board:	> 5 ans

Physical characteristics

Dimensions (W x H x L):	5.6 x 2.9 x 7.7 in (without power supply)
Weight:	1.55 lb (without power supply module)

Transport and storage conditions

Temperature:	-20°C to +60°C (-4°F to +140°F)
Relative humidity:	up to 95 % without condensation
Relative pressure range:	500 hPa to 1060 hPa (*1 hecto-Pascal ≃ 1 cmH_2O*)

Conditions of use

Temperature:	+5°C to +40°C (+41°F to +104°F)
Relative humidity:	between 10 % and 95 % without condensation
Relative pressure range:	700 hPa to 1060 hPa (*1 hecto-Pascal ≃ 1 cmH_2O*)
Operating Altitude:	0 to approximately 7,800 ft (0-2400 m)

Disposal of the GoodKnight 420 Evolution at the end of its life

In order to protect the environment, various parts of the equipment and its accessories must be disposed of in conformity with the local regulations.

Electrical characteristics of the power supply module

Class II power supply: Input voltage: 100 – 240 VAC (-10%, +10%), 50 / 60 Hz (±1 Hz)

Input current: 550 mA (Egston), 600 mA (Anam).

Output voltage: 13 V – 1.85 A (Egston) / 12 V – 2 A (Anam).

Power supply provided with the device: Egston N2UFMW 24 W 13 V or Anam TA2412 24 W 12 V.

CAUTION

- **Use only one of the above-mentioned specific power supplies provided with the device.**
- **The above-mentioned power supply modules are not intended to be repaired. In case of failure, please contact your service provider to have the module replaced.**

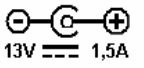
Electrical characteristics of the device

Input voltage: 13 V – 1.5 A.

Maximum power consumed: 20 W without humidifier

Current consumed at 20 cmH_2O with a 4 mm leak: 0,750 A.

Direct current



13 V power connector

Symbols

ON/OFF

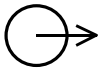
Information access

Ramp

PC connection

Increases setting values

Reduces setting values



Output connector

Device protected against the vertical falls of water drops.

Type B device

Consult the instructions for use before using this device.

Device complies with the requirements of the directive 93/42/CEE relating to medical appliances.

For USA only:
Federal law restricts this device for sale by or on the order of a physician.

Details of your Service Provider

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